DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the arguments filed on 11/04/2009.

2. Claims 9 and 20-22 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 11/04/2009 regarding the rejection of claims 9 and 20-22 made by the Examiner under 35 USC 103(a) over Hu (US 6132740) in view of Vonbehren et al. (US 2006/0115438) and Friedman et al. (US 2006/0269485) have been fully considered and they are found persuasive. The references to Vonbehren and Friendman do not qualify as prior art as they do not antedate Applicants priority date of 02/03/2003.

Priority

4. The instant application is a 371 filing of the PCT, not foreign priority. Applicants priority date is 02/03/2003.

Claim Objections

5. Claims 9 and 20-22 are objected to because of the following informalities: misspelling of the word 'isosorbide'. Applicants currently have it spelled 'isorbide'. A search of the phrase dimethyl isorbide resulted in no known structure. Appropriate correction is required.

New Rejections

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 9and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu (US 6132740; published 10/17/2000, of record) in view of Deckner (US 5,756,119) and Luzzi (US 4,711,904).**

9. Hu is directed to resorcinol derivatives and compositions containing them. Hu suggests formulating a composition with 4-cycloppentyl resorcinol (see column 3, lines 40-45). It's taught that the active ingredient (4-cyclopentyl resorcinol) may be present in an amount ranging from 0.01-10%, preferably between 0.1 -10% (see column 9, lines 50-55). Exemplified solvents include ethanol and propylene glycol (see column 12, lines 5-15) in a ratio of 7:3.

10. Hu fails to teach using hexylene glycol and dimethyl isosorbide in an amount of 5% and 15%, respectively.

11. Deckner is directed to enhanced skin penetration system for topical delivery of drugs. An exemplified drug is resorcinol (see column 4, lines 1-5). The composition is to contain solvents such as ethanol. The composition is to also contain humectants such as propylene and hexylene glycol that are to be contained in an amount up to 30% (see column 8, line 65). An optional co-solvent includes dimethyl isosorbide (see column 9, lines 25-30).

12. Luzzi is directed to treating skin disorders. It's taught that dimethyl isosorbide is a penetration enhancer and is quite effective in amounts of about 25% but can be as low as 1% or as high as 75% (see claim 2). Moreover, it's taught that dimethyl isosorbide possess beneficial antifungal and antibacterial properties (see abstract).

13. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hu, Deckner and Luzzi with a reasonable expectation for success in arriving at a composition comprising/consisting of 4-cyclopentyl resorcinol, dimethylisosorbide, hexylene glycol, propylene glycol and ethanol. Hu teaches a topical composition of 4-cyclpentyl resorcinol, ethanol and propylene glycol with 4-cyclopentyl resocrincol present at 5%, ethanol at 66% and propylene glycol at 28.5%. Deckner teaches topical may have a vehicle containing ethanol with a co-solvent of dimethylisosorbide. Humectants like hexylene glycol and propylene glycol may be included in an amount up to 30%. Luzzi teaches that dimethyl isosorbide is a useful skin penetration enhancer when used in an amount of 25%. It's noted that Luzzi suggests that dimethyl isosorbide could be used in an amount as low as 1%. It's the position of the Examienr that Applciants compositions are obvious. One would have been motivated to combine the ingredients at the instantly claimed percentages with a reasonable expectation for success. The composition of 4-cyclopentyl

resocrincol, ethanol and propylene glycol was known at the time Applicants invention was made. It would have been obvious to supplement said composition with other ingredients known to provide functional benefits to topically applied formulations. For instance, one would have included hexylene glycol into the composition with the expectation that its inclusion would provide skin moisturization to the user thereof. Moreover, the art acknowledges that it's effective over a wide range of concentrations, which are encompassed by Applicants claims. With respect to the inclusion of dimethyl isosorbide, this too is obvious as Deckner teaches that dimethyl isosirbide is a useful cosovlent for solubilizing agents such as resorcinol. One would have looked to the art to identify useful, workable concentrations and in doing so identified Luzzi which teaches that dimethyl isosorbide can be included in an amount of 1%-75% and at 25%. Luzzi recognizes additional benefits of including dimethyl isosorbide such as providing improved penetration benefit to active of the composition as well as imparting a antifungal and antibacterial benefit to the composition. Thus, if one arrived at a composition having dimethyl isosorbide in an amount of about 15%, then this would have been the product of ordinary skill and common sense. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
April 12, 2010

/David J Blanchard/
Primary Examiner, Art Unit 1643